K102082

510(k) SUMMARY

AUG 2 3 2010

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4872
Fax: 508-683-5939

Contact: Laurie Pannella, RAC
Regulatory Affairs Specialist
Date Prepared: July 23, 2010

2. Proposed Device:

Trade Name: Extractor™ Pro RX Retrieval Balloon, Extractor™ Pro XL Retrieval Balloon, and Extractor™ Pro DL Retrieval Balloon
Classification Name: Endoscopic Biliary Stone Retrieval Balloon Catheter (Catheter, Biliary, Diagnostic)
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

3. Predicate Device:

Trade Name: Extractor™ RX Retrieval Balloon
Manufacturer and Clearance Number: Boston Scientific Corporation, K041606
Classification Name: Endoscopic Biliary Stone Retrieval Balloon Catheter
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

Trade Name: Endoscopic Biliary Stone Retrieval Catheter
Manufacturer and Clearance Number: Boston Scientific Corporation, K931619
Classification Name: Catheter, Biliary, Surgical
Regulation Number: 876.5010
Product Code: GCA
Classification: Class II

Trade Name: Tri-Ex Extraction Balloon with Multiple Sizing
Manufacturer and Clearance Number: Wilson-Cook Medical, K040129
Classification Name: Catheter, Biliary, Surgical
Regulation Number: 876.5010
Product Code: GCA
Classification: Class II

4. Proposed Device Description:
Extractor™ Pro Retrieval Balloon Catheters are a stone retrieval balloon catheter used for biliary stone retrieval.

- The catheter may be placed with or without the aid of a guidewire.
- The catheter is capable of accepting a 0.035 in. (0.89 mm) guidewire
- Injection ports for contrast are set either below or above the retrieval balloon.

5. Intended Use:
The Extractor™ Pro Retrieval Balloon Catheters are indicated for use endoscopically to remove stones from the biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.

6. Technological Characteristics:
The proposed Extractor™ Pro Retrieval Balloon Catheters are similar in design, materials, and manufacturing processes to the predicate Extractor™ RX Retrieval Balloon (K041606) and Endoscopic Biliary Stone Retrieval Catheter (K931619).

7. Performance Data:
In-vitro testing has been performed and all components, subassemblies, and/or full devices met the required specifications.

8. Conclusion:
Boston Scientific Corporation has demonstrated that the proposed Extractor™ Pro Retrieval Balloon Catheters are substantially equivalent to Boston Scientific Corporation's currently marketed Extractor™ RX Retrieval Balloon (K041606) and Endoscopic Biliary Stone Retrieval Catheter (K931619).

Premarket Notification Truthful and Accurate Statement
(As Required by 21 CFR 807.87(k))

I certify that, in my capacity as a Regulatory Affairs Specialist at Boston Scientific Corporation, I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Laurie Pannella, RAC
Regulatory Affairs Specialist
Boston Scientific Corporation

July 23, 2010
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Laurie Pannella
Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

AUG 2 3 2010

Re: K102082
Trade/Device Name: Extractor™ Pro Retrieval Balloon Catheter
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: July 23, 2010
Received: July 26, 2010

Dear Ms. Pannella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102082

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~To Be Determined~~ K102082

Device Name: Extractor™ Pro Retrieval Balloon Catheter

Indications For Use: The Extractor™ Pro Retrieval Balloon Catheters are indicated for use endoscopically to remove stones from the biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K102082